REMARKS

There are no amendments to the claims.

Summary of the Basis for Rejection

Claims 11-14, 16-20, 22-23, 25, and 27-33 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,200,347 ("Anderson") in view of U.S. Patent No. 5,906,616 ("Pavlov").

The Applicants will address this sole basis for rejection in Section I, respectively, which follows.

I. 35 U.S.C. § 103(a) over Anderson in view of Pavlov

A. The Combination of Anderson and Pavlov Fail to Make a *prima facie* Case of Obviousness Against the Invention As Claimed

Claims 11-14, 16-20, 22-23, 25, and 27-33 are solely rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,200,347 ("Anderson") in view of U.S. Patent No. 5,906,616 ("Pavlov"). According to the Patent Office, "[w]ith respect to claims 11, 20, Anderson et al discloses an assembled implant, as best seen in the figures, for implantation between adjacent vertebrae in the spine of a patient comprising two or more sections of cortical bone; as best seen in FIGS. 1-10, that are **joined in tandem** by a pin (7, 9, 13) to form an implant that is longer than it is wide, as best seen in FI. 10 [sic], the pins interconnecting the section to form an **elongated body** from about 5mm to about 25 mm in length, wherein **all longitudinal surfaces are tapered and threaded** (since Anderson et al. disclose in column 6, lines 50-52, column 7, lines 1-13, surfaces including continuous protrusions) the elongated body also having also having a first diameter for initially engaging adjacent vertebrae and an opposing end having a second diameter that is larger than the first diameter (since Anderson et al. disclose in column 6, lines 39-40 that the bone graft is a tapered cylinder); as set forth in column 8, lines as set forth in column 23, lines 1-67, column 31, lines 1-22 and as best seen in the figures." [Official Action at page 2-3 (bridging sentence); emphasis added in bold.]

As an initial matter, the Applicants disagree with the Patent Office's characterization of FIG. 10. FIG. 10 is the only Figure in Anderson showing any assembled implant having a circular cross-section. However, FIG. 10 does not show an assembled implant "wherein **all longitudinal surfaces are tapered and threaded**." In fact, the Patent Office has admitted on page 3 of the office Action that "**Anderson did not teach of threads on the surface of the implant**. . ." Further, the assembled dowel of FIG. 10 is not tapered. A measurement of the diameter of each of the "cortical bone portions" of FIG 10 shows that the cross-section of each portion they has the same diameter. Moreover, Anderson's description of FIG. 10 at col. 20, lines 46-53 fails to state that the "cortical bone portions" or the "composite bone graft" are "tapered." Rather, Anderson says that "This [assembled] graft can be used in place of the traditional cloward dowel." [Anderson at col. 20, lines 52-53; emphasis added in bold.] One skilled in the art recognizes that the "traditional cloward dowel" is not a tapered dowel, but rather a straight dowel having a single diameter. *See* U.S. Pat. 6,743,257 (Castro) at col. 1, lines 60-64 ("Historically, two types of bone grafts have been available for anterior cervical fusion. One type is a **round dowel** plug-like configuration, such as the original **Cloward dowel**. The second type, a rectangular plug in a rectangular hole, is often referred to as the Smith-Robinson technique."); and U.S. Pat. 6,033,438 (Bianchi) at col. 2, lines 27-34 ("Several bone dowel products such as the **Cloward Dowel** have been developed over the years. Bone dowels in the shape of a generally circular pin can be obtained by drilling an allogeneic or autogeneic plug from bone. As shown in FIGS. 1 and 2, the dowels 100, 200 have one or two cortical surfaces 110 and an open, latticed body of brittle cancellous bone 120, 220 backing the cortical surface 210 or between the two cortical surfaces 110."); at col. 4, line 7 ("FIG. 1 shows a standard Cloward Dowel known in the art"); and at FIG. 1, showing the Cloward Dowel ; emphasis added in bold.

In addition to admitting that "**Anderson did not teach of threads on the surface of the implant**," the Patent Office also admits that "Anderson does not teach . . . **a slot** on the second end to drive the implant." [Official Action at page 3; emphasis added in bold.] To make up for these deficiencies, the Patent Office cites to Pavlov. However, Pavlov is directed to an anterior fusion "**cage**" that "defines an **internal cavity** and **apertures** through the wall of the cage which communicate the external cylindrical surface

with the internal cavity." [Pavlov at col. 1, lines 25-29.] Pavlov teaches that his "fusion cage" is made of a "**titanium metal** or **alloy** such as Ti64." [Pavlov at col. 9, lines 54-55; emphasis added in bold.] Pavlov also teaches the importance of having "**two or more flutes**" on the threads:

> **Without two or more flutes, wandering might occur** due to the fact that the thread is only substantially engaged with the vertebral bone structures and not with the disk material between the vertebral bone structures, which disk material does not provide support to the thread.
>
> [Pavlov at col. 2, lines 52-57; emphasis added in bold.]

One skilled in the art recognizes that the "**wandering**" of an implant between two vertebrae can be disastrous and may result in paralysis of a patient if the implant should contact the spinal cord. *See* U.S. Pat. 5,015,247 (Michelson) at col. 4, lines 18-21 ("5. ***Implant*** stability--Dislodgement of the ***implant*** would be a major source of device failure (an unsuccessful clinical result), and might result in patient ***paralysis*** or even death."). Thus, Pavlov teaches the **importance** of having "flutes" on the threads of an implant, whereas on the Applicants implants, such "flutes" are not found. *See Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) ("A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**"); emphasis added in bold.

Moreover, Pavlov teaches the use of "titanium metal or alloy" as the exclusive material for the body of its "cage" implant. Pavlov neither teaches nor suggests that cortical bone, as claimed by the Applicants, is a suitable equivalent of titanium for a continuously tapered and threaded implant that needs to be screwed into position. Anderson does not make up for this deficiency. As a matter of law, it is **impermissible** to use hindsight to **pick and choose** only certain parts of Pavlov (*i.e.*, threads), while disregarding others (flutes, titanium) to arrive at the Applicants' invention. *See Bausch & Lomb, Inc. v. Barnes-Hind Int'l, Inc.*, 230 USPQ 416, 420 (Fed. Cir. 1986), *quoting In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965) ("It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a

given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."). For all these reasons, the combination of Anderson and Pavlov fails to make a *prima facie* case of obviousness against claims 11-14, 16-20, 22-23, 25 and 27-33.

B. Claims 11-14, 16-20, 22-23, and 25 include an Element ("slotted") that is neither Taught nor Suggested in Anderson or Pavlov, Alone or in Combination

Separately, claims 11-14, 16-20, 22-23, and 25 each include as an element the recitation that one end of the implant is "slotted." Neither Anderson (as already admitted by the Patent Office) nor Pavlov discloses or suggests a cortical bone implant having a second end that is "slotted." Rather, Pavlov suggests the use of a "square" driver [col. 10, lines 52, 57 or 61] for a square hole; or a "tang [prong]" driver for insertion in "indentation [holes] 436 and 438" [col. 9, lines 36-37]. Thus, neither Anderson nor Pavlov, alone or in combination, teaches or suggests the "slotted" element as recited in claims 11-14, 16-20, 22-23 and 25. For these reasons, claims 11-14, 16-20, 22-23, and 25 of Applicants' invention would not have been obvious over Anderson in view of Pavlov.

C. Claims 27-33 include a Limitation ("pins suited for conveying a tortional load") that is neither Taught nor Suggested in Anderson or Pavlov, Alone or in Combination

Pavlov teaches the use of a single piece titanium cage that optionally has a cap. Pavlov neither teaches nor suggests the use of pins as components of its implantable cage for any purpose. Thus, the only reference teaching or suggesting the use of any pins is Anderson. Anderson teaches the use of pins for holding together adjacent pieces of a trapezoidal (FIGs. 1-5, 12, 33A-C, 36A-C, 39, 41-38), block-shaped (FIGs. 7-9, 11B, 13A, 27-32, 42A-C,), or D-shaped wedge (FIGs 14A-14C, 15, 35A-B, 37-38, 40A-B, and 43-44) implant. Each of these implants is characterized by having flat surfaces for contacting the opposing surfaces of opposing vertebrae. Because of their flat opposing (upper and lower) surfaces, none of these implants was constructed with pins suited for conveying tortional load during insertion. Rather, Anderson discloses that "the one or more pins and the one or more through holes are configured to provide an interference fit **for holding**

together the graft unit." [Anderson at col. 5, lines 25-28.] Thus, based upon the flat structure of the stacked implants shown in Anderson, the purpose of the pins in Anderson is merely as stated, "holding together the graft unit."

Likewise, the assembled dowel shaped implant of FIG. 10 is a series of donuts assembled in tandem with a **single** central pin having the same "interference fit" for simply "holding together the graft unit." Because Anderson discloses the use of a "**single**" **central pin** for the only dowel shaped implant disclosed therein, the graft of FIG. 10 would fail to teach the limitation in each of claims 27-33 to "**pins [plural] suited for conveying a tortional load**." As admitted by the Patent Office, "**Anderson did not teach of threads on the surface of the implant**. . . ." Accordingly, Anderson did not even perceive the problem of conveying torque along the length of a tandomly assembled threaded and continuously tapered circular implant of the Applicants' invention. As a matter of law, the invention as a whole "mandates" consideration of the "problem solved." *See In re Wright*, 6 USPQ2d 1959, 1962 (Fed. Cir. 1988) ("the requisite view of the whole invention **mandates** consideration of not only its structure but also its properties and the **problem solved**.") However, in the present case, Anderson failed to even perceive the problem and thus, could not suggest a solution. Pavlov's solution was to use an inherently strong titanium cage that was a **unitary** structure, and to add "flutes" to the threads to minimize the torque required to insert the implant by enhancing thread tapping. [See Pavlov at col. 2, lines 41-45 ("As with other embodiments of the present invention, **flutes** can be provided in the thread in order **to allow for enhanced thread tapping** by the cage and **for a smoother insertion of the fusion cage** between the vertebral bone structures.")] Thus, the combination of Anderson and Pavlov fails to address the problem of conveying torque along the length of a **tandomly "assembled"** continuously tapered and threaded circular implant of the Applicants' invention. Moreover, Anderson's approach with circular tandem implants was to use a **single** centrally positioned dowel having an interference fit for holding the adjacent pieces together. For all these reasons, the combination of Anderson over Pavlov would not have rendered obvious the invention as a whole of claims 27-33 of Applicants' invention. The allowance of claims 27-33 is respectfully requested.

CONCLUSION

Claims 11-14, 16-20, 22-23, 25, and 27-33-26 stand rejected. No claims have been added or amended. Accordingly, only previously submitted claims 11-14, 16-20, 22-23, 25, and 27-33-26 are pending.

In view of the amendments and arguments provided herein, all bases for rejection of claims 11-14, 16-20, 22-23, 25, and 27-33-26 under 35 U.S.C. § 103(a) for allegedly being obvious over Anderson in view of Pavlov have been rebutted.

For all these reasons, claims 11-14, 16-20, 22-23, 25 and 27-33 are in condition for allowance.

Respectfully submitted,

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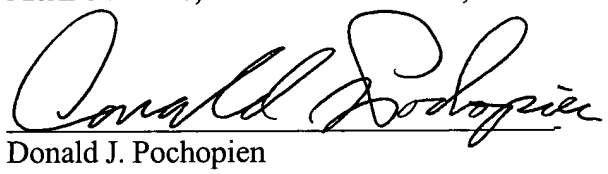
By: 

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